Urgent Field Safety Notice

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

GE Healthcare Ref: FMI 25465

<Date>

To: Hospital Administrators/Risk Managers
Managers of Radiology/Cardiology
Radiologists/Cardiologists

RE: **Revolution CT head image quality beam hardening artifact.**

GE Healthcare has recently become aware of a potential issue with routine head scans on your Revolution CT scanner. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

A potential hazardous situation can occur during a routine head scan with possible artifacts that may emulate pathology between the brain tissue and bone in the head images. No injuries have been reported to date related to this issue.

Safety Instructions

You can continue to use your Revolution CT product. For routine head scans, GE Healthcare recommends that you position the patient head so that the orbital-meatal line is parallel to the scan plane and that you use GE Protocols 21.1 or 21.2 (see addendum). To further reduce the appearance of beam hardening artifacts, use 40mm collimation.

Introducing 40mm collimation for routine head scans will result in more table transitions, so sites should determine if 40, 80, 120 or 160mm collimation for head imaging best meets the needs of your radiology practice.

When performing head scans, be sure to follow the CT User Manual for information on how to help minimize these types of artifacts during routine head scans. The information and warnings can be found in your Revolution CT User Manual (5480385-1XX Rev 2).
For potential artifacts during scanning:

- Safety Chapter (Chapter 3, Section 14.1).

For beam hardening issues for head scans:

- Scan Chapter (Chapter 11, Section 4.5.4.2)
- Pediatric and Small Patient Chapter (Chapter 5, Section 3.5.5)
- General Information Chapter (Chapter 21, Section 6.1).

Product Correction

To minimize the effects of beam hardening artifacts during routine head scans, GE Healthcare recommends that in addition to the information in the existing CT User Manual, the site also follow the additional recommendations listed in the safety instructions above. GE Healthcare will be delivering an addendum to the User Manual that reiterates these mitigations.

Additional improvements to image quality are currently in development. This software will be distributed and installed on your system at no cost to you.

Affected Product Details

Revolution CT Scanners, software version 15MW03.12

Contact Information

If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,

James W. Dennison
Vice President Devices
GE Healthcare

Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare